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Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

MAILED
JUN - 5 2012
OPLA

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,733,767 was filed on November 9, 2011, under 35 U.S.C. § 156. Please note that the application for patent term extension was filed using the United States Patent and Trademark Office's (USPTO) electronic filing system (EFS). Original applications for patent term extension are prohibited from being filed via the USPTO's EFS. Applicant has petitioned for waiver of the prohibition. The petition has been granted.

The assistance of your Office is requested in confirming that the product identified in the application, LONGRANGE (eprinomectin), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be **NOT** eligible for extension of the patent term under 35 U.S.C. § 156.

One of the eligibility requirements, 35 U.S.C. § 156(a)(5)(A), is that the permission for commercial marketing or use of the product must be the **first** permitted commercial marketing or use of the "product" under the provision of law under which such regulatory review period occurred. The definition of "product" is explicitly set forth in the statute at subsection (f). There, the statute defines "product" as "drug product" and in turn defines "drug product" as "the active ingredient of a new drug, . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient." See § 156(f)(2). Thus, the relevant inquiry is whether the active ingredient of LONGRANGE™, i.e., eprinomectin, is the first permitted commercial marketing or use of eprinomectin as reviewed under section 512 of the FFDCA. Based on Applicant's disclosure and information obtained from FOIA Drug Summaries,[1] the

[1]http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/default.htm

USPTO finds that the permission to commercially market or use LONGRANGE™ does not constitute the first permitted commercial marketing or use of eprinomectin as required by section 156(a)(5)(A).

Applicant notes that the active ingredient of LONGRANGE™ is eprinomectin. Application at 2. Applicant also notes that a formulation of eprinomectin as a Pour-On for Beef and Dairy Cattle has been previously approved under section 512 of the FFDCA. Application at pages 2-3. FDA records also indicate that eprinomectin has been approved prior to the approval of LONGRANGE™. See, e.g., approval information of IVOMEC EPRINEX, attachment 1. Since it is apparent that the permission to commercially market and use eprinomectin formulated in the animal drug product LONGRANGE™ does **not** constitute the first permitted commercial marketing or use of eprinomectin, U.S. Patent No. 6,733,767 is **not** eligible for extension. Please confirm that the USPTO is correct in their assessment of compliance with the requirements of 156(a)(5)(A) regarding the permission for commercial marketing or use of LONGRANGE™ on September 26, 2011.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Sylvia A. Ayler
Merck, Sharp & Dohme Corp.
Patent Department
P.O. Box 2000
Rahway, NJ 07065-0907